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NORTH COAST WOMEN'S CARE RESEARCH FACILITY EXPERIENCE

Jan 2007-2012

Clinical Study Protocol #511.84
A Twelve Month, Open-label, Safety Trial of XXX 50 milligrams to
100 milligrams Daily in Women with Hypoactive Sexual Desire Disorder

Principal Investigator:	Douglas K. Fenton, MD
Subinvestigators:	Christine Z. Brody, MD
	Charles E. Stoopack, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
	Rumiko Harkness CRNP
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	15 patients
Screened:	28
Enrolled:	28

Jan 2007-2012

Clinical Study Protocol #108933 HPV 010
A Phase IIIb, Observer-blind, Randomized, Multicenter

Study with Two
Parallel Groups to Compare the Immunogenicity of XXX Vaccine versus Merck's Gardasil Vaccine when administered Intramuscularly According
to a 3-dose Schedule in Healthy Females 18-45 years of age.

Principal Investigator:	Douglas K. Fenton, MD
Subinvestigators:	Christine Z. Brody, MD
	Charles E. Stoopack, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN MN
Target Enrollment:	75 patients
Screened:	40 patients
Enrolled:	40 patients

Dec. 2006-Apr. 2007 Clinical Study Protocol #FENHYDPAI4003

A Multicenter, Double-blind, Randomized, Placebo-controlled, Multiple-dose, Parallel Group Study to Determine Time of Onset of Pain Relief Using Standard Regimen of Morphine via Intravenous PCA following Total
Abdominal Hysterectomy

Principal Investigator:	Christine Z. Brody, MD
Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	5 patients
Screened:	6 patients
Enrolled:	5 patients

Dec 2006-Feb. 2008 Clinical Study Protocol #DR-ASC-201

A Prospective, Multicenter, Double-blind, Randomized, Study to Evaluate Bleeding Patterns in Women Using One of Three Different Ascending EE
Dose Extended-Cycle (91-Day) Oral Contraceptive Regimens (XXX)
Compared to Seasonale Oral Contraceptive Regimen

Principal Investigator:	Christine Z. Brody, MD

Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Shambra Rodriguez MA
Target Enrollment:	15 patients
Screened:	15 patients
Enrolled:	10 patients

July 2006-present Clinical Study Protocol #511.70

A Twenty-Four week, Randomized, Double-Blind, Placebo-Controlled,
Safety and Efficacy Trial of X mg of XXX twice daily and X mg once
and twice daily in Premenopausal Women with Hypoactive Sexual Desire Disorder in North America

Principal Investigator:	Charles E. Stoopack, MD
Subinvestigators:	Christine Z. Brody, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
	Rumiko Harkness CRNP
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	18 patients
Screened:	36 patients
Enrolled:	36 patients

July 2006-July 2007 Clinical Study Protocol #DR-DZL-201

A Phase 2, Multicenter, Double-blinded, Randomized, Placebo-controlled
Study to Evaluate Two Doses of XXX Vaginal Ring for the Management of Moderate to Severe Endometriosis-Related Non-menstrual Pelvic Pain

Principal Investigator:	Christine Z. Brody, MD
Subinvestigators:	Charles E. Stoopack, MD

Douglas K. Fenton, MD
Ross M. Langley, MD
Lynne Calkins CRNP
Study Coordinator: Mary K. Fenton, RN, MN
Target Enrollment: 3 patients* (*Sponsor closed study prematurely)
Screened: 16 patients
Enrolled: 1 patient

July-December 2006 **Clinical Study Protocol# 3142A2-203-WW**
A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the
Safety and Efficacy of X mg and X mg Doses of XXX on the Reduction of Symptoms Associated with Endometriosis during Treatment and
Post-Treatment in Reproductive-Aged Women

Principal Investigator: Christine Z. Brody, MD
Subinvestigators: Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD
Lynne Calkins CRNP
Study Coordinator: Mary K. Fenton, RN, MN
Target Enrollment: 3 patients
Screened: 5 patients
Enrolled: 3 patients* (*Sponsor closed study prematurely)

April 2006-Dec 2006 **Clinical Study Protocol #1VIT06011**
Comparison of the Safety and Efficacy of a Unique Intravenous Iron
Preparation XXX versus Oral Iron in Subjects who Display Postpartum
Anemia

Principal Investigator: Christine Z. Brody, MD
Subinvestigators: Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD
Lynne Calkins CRNP
Study Coordinator: Mary K. Fenton, RN, MN
Target Enrollment: 10 patients
Screened: 22 patients
Enrolled: 14 patients

March 2006-Nov. 2007 **Clinical Study Protocol #3115A1-304-WW**

A Double-Blond, Randomized, Placebo and Active Controlled Efficacy and Safety Study of XXX for Prevention of Endometrial Hyperplasia and Prevention of Osteoporosis in Postmenopausal Women

Principal Investigator:	Douglas K. Fenton, MD
Subinvestigators:	Christine Z. Brody, MD
	Charles E. Stoopack, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN MN
Target Enrollment:	10 patients
Enrolled:	20 patients

Oct-Dec 2005 **Clinical Study Protocol #DOV-075-024**

A Multi-center, Double-blinded, Placebo-controlled, Randomized Study of
XXX for the Treatment of Post-operative Pain Following Vaginal
Hysterectomy

Principal Investigator:	Charles E. Stoopack, MD
Subinvestigators:	Christine Z. Brody, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN, MD
Target Enrollment:	8 patients
Screened:	4 patients
Enrolled:	*2 patients (*Sponsor closed study prematurely)

May 2005-Feb 2006 **Clinical Study Protocol #1VIT03001**

Comparison of the Safety and Efficacy of a Unique Intravenous Iron
Preparation (XXX) versus Oral Iron in Subjects Who Display
Postpartum Anemia

Principal Investigator:	Christine Z. Brody, MD

Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	10 patients
Screened:	13 patients
Enrolled:	*7 patients (*Add-on Site)

May-Sept 2005 **Clinical Study Protocol #1VIT04003**

Comparison of the Safety and Efficacy of a Unique Intravenous Iron Preparation (XXX) versus Oral Iron in the Treatment of Iron Deficiency Anemia Secondary to Heavy Uterine Bleeding

Principal Investigator:	Christine Z. Brody, MD
Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Lynne Calkins CRNP
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	10 patients
Screened:	22 patients
Enrolled:	10 patients

May 2004 – April 2005 **Clinical Study Protocol # CAPSS 320**

Comparison of the Safety and Efficacy of Patient Controlled Analgesia
Delivered by XXX versus Morphine IV Pump for Pain Management
After Non-emergent Abdominal Surgery

Principal Investigator:	Christine Z. Brody, MD
Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Darcey B. Perlman, MD
Study Coordinator:	Mary K. Fenton, RN, MN
Target Enrollment:	12 patients
Screened:	59 patients
Enrolled:	48 patients

May-Aug 2004 **Clinical Study Protocol #11658-001**

A Prospective Evaluation of the Burden of Post-Operative Ileus and
Opioid Bowel Dysfunction in Patients Undergoing Abdominal Surgery

Principal Investigator:	Douglas K. Fenton, MD
Subinvestigators:	Christine Z. Brody, MD
	Charles E. Stoopack, MD
	Ross M. Langley, MD
	Darcey B. Perlman, MD
Study Coordinator:	Mary K. Fenton, RN MN
Target Enrollment:	8 patients
Screened:	8 patients
Enrolled:	8 patients

2004 **Clinical Study Protocol #BT0300C1-300-USA**

Comparison Study of the Safety and Efficacy of a Single Dose of XXX
versus a Single Dose of XXX in the Treatment of Vaginal Candidiasis

Principal Investigator:	Christine Z. Brody, MD
Subinvestigators:	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Darcey B. Perlman, MD

2004 **Clinical Study Protocol #2004031**

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter, 52 week study to evaluate the efficacy and safety of
XXX in menopausal women with low libido not receiving systemic estrogen or estrogen progestin therapy

Subinvestigators:	Christine Z. Brody, MD
	Charles E. Stoopack, MD
	Douglas K. Fenton, MD
	Ross M. Langley, MD
	Darcey B. Perlman, MD

2003-2004 **Clinical Study Protocol #CFAM810A US07**

An Open Label, Single-Arm Multicenter study to evaluate the safety and
efficacy of XXX in the episodic treatment of Recurrent Genital Herpes,
XXX for 5 days, and in the suppressive treatment of Recurrent Genital
Herpes, XXX for 6 months

Principal Investigator: Charles E. Stoopack, MD
Subinvestigators: Christine Z. Brody, MD
Douglas K. Fenton, MD
Ross M. Langley, MD
Darcey B. Perlman, MD
Study Coordinator: Mary K. Fenton, RN, MN

2002- 2003 **Clinical Study Protocol #OXY-MD-10-000**

A Double-blind, Placebo and Comparator Controlled, Single-Dose
Parallel Study of the analgesic efficacy and safety of XXX in female
patients with moderate to severe post-abdominal or pelvic surgical pain

Principal Investigator: Christine Z. Brody, MD
Subinvestigators: Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD

2002 **Clinical Study Protocol #2002005**

A Phase III, Multi-national, Randomized, Double-blind, Parallel Group,
Placebo-controlled Study to evaluate the efficacy and safety of XXX
for 24 weeks and safety for a further 28 weeks in naturally menopausal
women with Hypoactive Sexual Disorder on concurrent oral hormone replacement therapy

Subinvestigators: Christine Z. Brody, MD
Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD
Darcey B. Perlman, MD

2002 **Clinical Study Protocol # 2001134**

A Phase III, Multi-national, Randomized, Double-Blind, Parallel Group, Placebo-controlled 24 week study to evaluate the safety and efficacy of XXX in women with hypoactive sexual desire disorder on concurrent estrogen replacement therapy who have undergone hysterectomy and bilateral oophorectomy

Subinvestigators: Christine Z. Brody, MD
Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD
Darcey B. Perlman, MD

2001-2003 **Clinical Study Protocol #14CL306**

A Multicenter Phase III, Double-blind, Placebo Controlled Study of XXX in Opioid-induced Postoperative Bowel Dysfunction/Postoperative Ileus in subjects undergoing Total Abdominal Hysterectomy

Principal Investigator: Christine Z. Brody, MD
Subinvestigators: Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD

2000-2002 **Clinical Study Protocol #14CL302**

A Multicenter Phase III, Double-blind, Placebo Controlled Study of XXX in Opioid-induced Postoperative Bowel Dysfunction/Postoperative Ileus

Principal Investigator: Christine Z. Brody, MD
Subinvestigators: Charles E. Stoopack, MD
Douglas K. Fenton, MD
Ross M. Langley, MD

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